Sec.
242.4 Definitions.
242.5 Eligibility for subsistence use.
242.6 Licenses, permits, harvest tickets, tags, and fees.
242.7 Restriction on use.
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Subpart B—Program Structure.

242.10 Federal Subsistence Board.
242.11 Regional advisory councils.
242.12 Local advisory committees.
242.13 Board/agency relationships.
242.14 Relationship to State procedures and regulations.
242.15 Rural determination process.
242.16 Customary and traditional use determination process.
242.17 Determining priorities among subsistence users.
242.18 Regulation adoption process.
242.19 Closures and other special actions.
242.20 Request for reconsideration.
242.21 [Reserved]

Subpart C—Board Determinations

242.22 Subsistence resource regions.
242.23 Rural determinations.
242.24 Customary and traditional use determinations.

Authority: 16 U.S.C. 3, 472, 551, 668dd *et seq.*, 3101 *et seq.*; 18 U.S.C. Chapter 227; 43 U.S.C. 1733.

TITLE 50—WILDLIFE AND FISHERIES

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

Part 100 of title 50 is proposed to be revised as set forth at the end of the common rule.

PART 100—SUBSISTENCE MANAGEMENT REGULATIONS FOR FEDERAL PUBLIC LANDS IN ALASKA

Subpart A—General Provisions

Sec.
100.1 Purpose.
100.2 Authority.
100.3 Applicability and scope.
100.4 Definitions.
100.5 Eligibility for subsistence use.
100.6 Licenses, permits, harvest tickets, tags, and fees.
100.7 Restriction on use.
100.8 Penalties.
100.9 Information collection requirements.

Subpart B—Program Structure

100.10 Federal Subsistence Board.
100.11 Regional advisory councils.
100.12 Local advisory committees.
100.13 Board/agency relationships.
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100.15 Rural determination process.
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100.17 Determining priorities among subsistence users.
100.18 Regulation adoption process.
100.19 Closures and other special actions.
100.20 Request for reconsideration.
100.21 [Reserved]

Subpart C—Board Determinations

100.22 Subsistence resource regions.
100.23 Rural determinations.
100.24 Customary and traditional use determinations.

Authority: 16 U.S.C. 3, 472, 551, 668dd *et seq.*, 3101 *et seq.*; 18 U.S.C. Chapter 227; 43 U.S.C. 1733.

John F. Turner,

Director, U.S. Fish and Wildlife Service.

Michael A. Barton,

Regional Forester, USDA—Forest Service.

[FR Doc. 92-2141 Filed 1-29-92; 8:45 am]

BILLING CODES 3410-11-M; 4310-55-M

federal register

Thursday
January 30, 1992

Part III

Department of Education

Foreign Languages Assistance Program; Notice

DEPARTMENT OF EDUCATION

Foreign Languages Assistance Program

AGENCY: Department of Education.

ACTION: Final interpretations and designation of critical foreign languages.

SUMMARY: For the purposes of the Foreign Languages Assistance Act of 1988, authorized by title II, part B, of the Elementary and Secondary Education Act, the Secretary designates Chinese (all dialects), Japanese, Korean, Arabic (all dialects), and Russian as the primary critical foreign languages. The Secretary also establishes, for a State that can clearly document that it lacks the capability to implement model programs in any of those languages, a procedure under which the State educational agency (SEA) may apply for a waiver of the requirement to fund model programs only in the designated primary languages. An SEA that is granted a waiver may use funds under this program to support model programs in any of the alternate critical languages of French, German, Italian, Portuguese, and Spanish. The Secretary also provides certain interpretations of other portions of the Act that are needed to administer the program.

EFFECTIVE DATE: These interpretations take effect either March 16, 1992, or later if the Congress takes certain adjournments, except that the provision for obtaining the Secretary's approval to support model projects in French, German, Italian, Portuguese, or Spanish, will become effective after the information collection requirements contained in those sections have been submitted by the Department of Education and approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980. If you want to know the effective date of these interpretations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Doris Crudup, School Effectiveness Division, U.S. Department of Education, 400 Maryland Avenue, SW., Washington, DC 20202–6140, (202) 401–1062. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: The Foreign Language Assistance Program is authorized by title II, part B, of the Elementary and Secondary Education Act of 1965, as amended by the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100–297). It is a new formula grant program that is intended to provide financial assistance to State educational agencies (SEAs) to improve the quantity and quality of instruction at both the elementary and secondary school levels in those foreign languages that are critical to the economic and security interests of the United States. Specifically, the Foreign Languages Assistance Program provides support for model programs that will assist school districts in their efforts to help move the Nation toward accomplishing National Education Goal Number 3, which has, as one of its objectives, increasing the percentage of students who are competent in more than one language. The program outlined in this notice can help States and localities make schools better and more accountable for today's students—a major aim of AMERICA 2000, the President's education strategy.

Congress has appropriated $4.9 million for fiscal year 1991 and $10 million for fiscal year 1992 to implement this program. Under the statute, each SEA distributes funds on a competitive grant basis to local educational agencies (LEAs) for model programs they have designed that represent alternative and innovative approaches to foreign language instruction. Unless the Secretary grants a waiver, the non-federal matching requirement is 50 percent. Because each SEA's application must describe the model projects to be conducted, the Secretary is announcing the criteria under which the Foreign Languages Assistance Program will be administered.

On April 29, 1991, the Secretary published a notice of proposed interpretations and designation of critical foreign languages for the Foreign Languages Assistance Program in the **Federal Register** (56 FR 19645). The notice proposed certain statutory interpretations that would apply to all projects that the program would fund. In addition, the Secretary proposed to designate Chinese (all dialects), Japanese, Korean, Arabic (all dialects), and Russian as the only foreign languages whose instruction the program would support.

The major difference between the proposed interpretations and these final interpretations is inclusion of procedures under which an SEA may apply for a waiver of the requirement that it fund model programs only in the primary languages designated by this notice.

Analysis of Comments and Changes

The Department received forty-six comments on the proposed interpretations. An analysis of the comments and of the portions of this notice that reflect changes from the proposed interpretations follows.

Major issues are grouped according to subject, with appropriate sections of the statute (if any) referenced in parentheses.

Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

The Critical Foreign Languages

Comments: Nearly all of the comments received addressed the proposed designation of Chinese (all dialects), Japanese, Korean, Arabic (all dialects), and Russian as the only critical foreign languages for purposes of this program. Many of the respondents disagreed with the proposed designation and recommended that it be expanded to include other languages. Some recommended that the foreign languages specified in the proposed notice be given priority, but that other languages be added. Other commenters recommended that the list of 169 languages designated in a notice published in the **Federal Register** on August 2, 1985 (50 FR 31412), for programs at the postsecondary level, serve as the list of "critical" foreign languages for this program.

Many commenters felt that limiting the program to the five languages as proposed would make it difficult for some States and localities to participate in the program because they lack qualified teachers or the necessary financial resources. Some commenters stated that, because the proposed languages are considered of "high difficulty" for English speakers and very few universities offer programs for teacher preparation in these languages, new programs in these languages would require careful planning and the development of a sequential program with implementation over an extended period of time. Other commenters stated that the proposed designation would require States and LEAs to create programs that do not presently exist and for which there is no guarantee of long-term funding. Commenters pointed out that few elementary schools offer instruction in any foreign language, and suggested that restricting the use of funds to instruction in the proposed five languages would not encourage States or LEAs to begin foreign language programs at the elementary level.

Some commenters recommended that the decision as to what constitutes a "critical" foreign language be left to each State. According to these commenters, the definition of "critical" varies from State to State and is often determined by geographical location, ethnic population, and primary sources of trade for that State.

Five commenters supported the designation of the five critical foreign languages as proposed. These commenters felt that the designation would allow necessary resources to be focused on crucial, yet widely neglected, languages. They also suggested that expanding the list of critical languages would divert support from these less commonly taught languages, diluting the impact of the legislation. Some commenters noted that there are few models for programs in Chinese, Japanese, Korean, Russian, and Arabic, and that the Foreign Languages Assistance Program could serve as a catalyst to support the creation of model programs in these languages.

Discussion: The authorizing statute requires the Secretary to designate the "critical" foreign languages. This responsibility cannot be delegated to the States or LEAs. In carrying out this responsibility, the Secretary believes that to designate all 169 languages from the August 2, 1985 **Federal Register** notice would not meet the intent of the legislation to establish model foreign language programs at the elementary and secondary levels that promote "the economic and security interest of the Nation." The 1985 list was associated with a postsecondary education program, and was developed to identify languages important to scientific inquiry and research as well as of national security and economic interest.

The Secretary believes that the primary objectives of the Foreign Languages Assistance Program would best be served by focusing resources on a select group of less commonly taught, but highly critical, foreign languages, and that the emphasis on Chinese, Japanese, Korean, Arabic, and Russian would best serve the economic and security interests of the United States. This interpretation is consistent with the report of the Senate Appropriations Committee that accompanied the fiscal year 1991 appropriation for this program. In that report, the Senate expressed its intent that the program "focus primarily on the less commonly taught languages."

The Secretary recognizes, however, that Congress enacted the Foreign Languages Assistance Program as a State formula grant program, presumably with the intent that all States be able to participate. Consequently, the Secretary agrees that a State should not be precluded from participation in the program solely because LEAs in the State are unable to procure trained teachers or other resources needed to operate model programs in one of the languages proposed in the April 1991 **Federal Register** notice. For this reason, the Secretary has determined that an SEA that can demonstrate either (1) a clear lack of resources needed to implement model programs in Chinese, Japanese, Korean, Arabic, and Russian, or (2) other compelling reasons, may obtain a waiver to implement model programs in the more commonly taught languages of French, German, Italian, Portuguese, and Spanish. The section of this notice on "Application Content" describes the information that the Secretary will review in considering any SEA's request for a waiver.

The Secretary anticipates, however, that few requests for waivers are likely to be granted. To make a convincing case for approval to undertake projects in the five alternative languages, an SEA must demonstrate that the lack of available qualified teachers or other resources throughout the State or region, or other compelling reasons make it impossible for any LEA in the State to develop and implement model programs in Chinese, Japanese, Korean, Arabic, or Russian. An SEA's supporting evidence might include the following kinds of data: Surveys of school districts and universities to determine the availability of teachers in those languages, a comparison of the costs of implementing projects in the five critical languages with the costs of projects in the five alternate languages, accompanied by an analysis of local and State resources available for implementing projects in each group of languages, or descriptions of programs proposed by LEAs in the primary languages accompanied by an explanation for the SEA's rejection.

Furthermore, this program is not designed to support long-term projects. Rather, awards are to be made for a three-year period, and funds are to be used to develop models that can be replicated in other locations. The argument by some commenters that the "difficulty" of the designated language will deter LEAs from establishing model programs in elementary schools is not persuasive. In fact, because experience seems to show that young children have less difficulty learning a foreign language than older children or adults, it is likely that many of the most promising projects will be proposed for the elementary level. Finally, States should note that, although the statute requires a 50 percent State and local match, the law makes provisions for applying to the Secretary for a waiver of that requirement.

Changes: The Secretary has changed the definition of "critical foreign languages." The languages of Chinese, Japanese, Korean, Arabic, and Russian are now designated as the primary critical foreign languages, and, absent a waiver, all States will be required to fund local model programs in those languages. However, the definition also now includes French, German, Italian, Portuguese, and Spanish as alternate critical foreign languages. In order to fund model programs in any of the alternate languages, a State will have to apply for a waiver from the basic requirement and gain the approval of the Secretary. The section of this notice on "Application Content" has been modified to reflect this change.

Program Application

Comments: Commenters asked if (1) the State application is to be for a one- or three-year period; (2) a State application that merely describes the State's plan for selecting model programs can be approved prior to the identification of the LEA model programs; and (3) the LEA application must be developed for a three-year period. One commenter suggested that the Secretary define what is meant by a "model" program.

Discussion: The Act requires that a description of the model programs designed by LEAs be included in the State application. It further states that funds "shall be made available to the State two additional years after the first fiscal year during which the State receives its allotment" if the funds in the first year were used in the manner required under the State's approved application. Therefore, the Secretary will require that State applications cover a three-year period, pending the availability of appropriations. The State application must contain a description of model programs that have been selected on a competitive basis prior to submission of the application. While the statute requires that funds be used to support model programs for the commencement or improvement and expansion of foreign language study, the Secretary believes that the actual definition and duration of a model program is best determined by the SEA.

Changes: The application procedures have been amended to require that State applications cover a three-year period.

Participating Children

Comments: Commenters questioned the proposed requirement that children aged 5 through 17 who reside in the school district of the LEA must be eligible to participate in the program. One commenter recommended that SEAs be required to identify the mechanisms to be used to ensure that the programs will be available to children attending private schools or that the Secretary require LEAs to set aside funds to be allocated to private elementary and secondary institutions located in the LEA to implement programs. Other commenters noted that the requirement that the State's application contain an assurance that "all children * * * who reside in the school district of the LEA" must be able to participate in the program could limit participation by LEAs and restrict the programs to magnet schools. Another commenter pointed out that the language in the notice differed from language in other legislation, such as chapter 2 of title I of the ESEA, or the Drug Free Schools and Communities Program, and that private school children to be served under those programs are identified as those children attending school within the boundaries of a program or project. However, under the Foreign Languages Assistance Program eligibility for participation is extended to all children residing in the LEA.

Discussion: Section 2103(b)(2) of the Act requires that the SEA provide an assurance that all children, enrolled in public or private schools, who reside in the school district be eligible to participate in any model program funded under the Foreign Languages Assistance Program. In addition, section 2103(d) of the Act requires that, to the extent consistent with the number of children in the State or in the school district of each LEA who are enrolled in private elementary and secondary schools, each State or LEA shall, after consultation with appropriate private school representatives, make provision for including special services in which children attending private schools can participate. Because section 2103(a) limits activities to model programs "designed and operated by local educational agencies," the statute does not authorize these services to private school children to be provided out of funds that would be separately allocated to private institutions.

Furthermore, the Secretary believes that, as a practical matter, Congress could not have intended to require all LEAs to implement model programs for which all children, regardless of age and grade level, are eligible to participate, or to issue conditions that would restrict model programs to magnet school sites. Therefore, the proposed and final interpretations continue to require that participation in model programs be open to all children in the grade level or levels for which the model was designed rather than all children ages 5 through 17.

Changes: None.

Non-Federal Share

Comments: One commenter urged that the interpretation specify that no new funds be required for the 50 percent match and that the matching requirement be ignored.

Discussion: the law explicitly requires a 50 percent match, with provision for a waiver for those States able to demonstrate significant hardship.

Changes: None.

Applicable Regulations

The Education Department General Administrative Regulations (EDGAR) in 34 CFR part 76 (State-Administered Programs), part 77 (Definitions that Apply to Department Regulations), part 79 (Intergovernmental Review of Department of Education Programs and Activities), part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), part 81 (General Education Provisions Act—Enforcement), part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-free Workplace (Grants)), and part 86 (Drug-Free Schools and Campuses).

Authority: 20 U.S.C. 2981–2991, 2993

Definitions and Interpretations

The Critical Foreign Languages

Section 2105 of the Act defines the term "foreign language instruction" as "instruction in critical foreign languages as defined by the Secretary." For the Foreign Languages Assistance Program, the Secretary designates Chinese (all dialects), Japanese, Korean, Arabic (all dialects), and Russian as the primary critical foreign languages. An SEA that can document a clear lack of capability to fund local model projects in any of these primary languages, which would preclude its participation in the program, may apply to the Secretary for approval to support, instead, local model projects in one or more of the alternate critical foreign languages. For the purposes of this program, the alternate languages are French, German, Italian, Portuguese, and Spanish. An Sea that wishes to apply for a waiver in order to support model programs in one or more of the alternate languages must provide justification as discussed under the next section of this notice.

Application Content

Section 2103(b) of the Act requires that an Sea desiring to receive a grant shall submit an application to the Secretary that covers three fiscal years and contains information and assurances as the Secretary may require. Consistent with the purpose of the program, all applications must include information that will ensure that projects contribute to the statutory goal of developing model programs from which other schools in the Nation can benefit. In addition, applications must include the following information as well as the items enumerated in section 2103(b) of the statute:

(1) A description of how each model program could benefit other school systems in the Nation;

(2) A description of how each program's design will provide a reliable measure of the impact of the program or of student educational achievement; and

(3) An assurance that, upon completion of each program, the SEA will provide to the Secretary documentation and a final evaluation of the program, in a form suitable for dissemination to other schools or school districts that may wish to replicate the program.

In addition, an application requesting approval from the Secretary to support model programs in one or more of the secondary critical foreign languages of French, German, Italian, Portuguese, or Spanish, must specifically describe:

(1) Efforts made by the State to identify and inform LEAs about, personnel and resources that LEAs can use in designing and implementing programs in the five primary critical languages (Chinese, Japanese, Korean, Arabic, or Russian);

(2) Use of criteria to select model programs that give additional weight to proposed programs offering instruction in one of the five primary critical languages:

(3) Reasons for the inability to fund projects in any of the five primary languages; and

(4)Any other conditions or circumstances that would clearly preclude implementation of model programs in any of the five primary critical languages.

In deciding whether to grant a waiver to an SEA from the basic requirement that it fund local model projects exclusively in one or more of the five primary languages designated in this

notice, the Secretary will consider whether the SEA's application demonstrates that, without a waiver, the State clearly would be unable to participate in the program. The Secretary will look for evidence that LEAs in the State are unable to implement model projects in the primary languages because either (1) an inability to procure qualified teachers or other needed resources, or (2) other compelling reasons. The Secretary will not consider local or State preference as a compelling reason for granting a waiver.

Program Variety

In approving an SEA's plan, the Secretary takes into consideration the amount of program funds that each State receives in determining whether the State's model programs represent a variety of alternative and innovative approaches to foreign language instruction, as required by section 2103(b)(1)(B) of the Act.

Participating Children

Section 2103(b)(2) of the Act requires and SEA's application to contain an assurance that "all children aged 5 through 17 who reside within the school district of the local educational agency shall be eligible to participate in any model program" funded under the Foreign Languages Assistance Act. The Secretary interprets this provision to mean that, for whatever grade span a model program is designed, all children in those grade levels who reside within the area served by the LEA must be eligible to participate.

Non-Federal Share

Section 2103(b)(3) of the Act requires that an SEA's application contain an assurance "that the state will pay the non-Federal share of the activities for which assistance is sought from non-Federal sources." For purposes of this program, this means that the source of the non-Federal share will be either State or local. In either case, the contribution must come from non-Federal sources. In addition, the requirement of a 50 percent non-Federal share of project costs includes both these costs and third party in-kind contributions that are allowable under § 80.24 of EDGAR.

Waiver of Non-Federal Share

Section 2103(c)(2) of the Act authorizes the Secretary to waive the requirement of a 50 percent State or local share if the Secretary determines that adequate resources are not available. Consistent with the intent of Congress in enacting the waiver provision (see S. Rep. No. 222, 100th Cong., 1st Sess. 76 (1987)) the Secretary will grant a waiver only if presented with a clear case of hardship.

Program Authority: 20 U.S.C. 3001–3006.

Dated: January 22, 1992.

Lamar Alexander,

Secretary of Education.

[FR Doc. 92–2219 Filed 1–29–92; 8:45 am]

BILLING CODE 4000–01–M

federal register

Thursday
January 30, 1992

Part IV

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice of Approved Tribal-State Compact

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary–Indian Affairs, Department of the Interior, through his delegated authority has approved a Tribal-State Compact between the Oneida Tribe of Indians of Wisconsin and the State of Wisconsin executed on November 8, 1991.

DATES: This action is effective upon date of publication.

ADDRESSES: Office of Tribal Services, Bureau of Indian Affairs, Department of the Interior, MS/MIB 4603, 1849 "C" Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Joyce Grisham, Bureau of Indian Affairs, Washington, DC 20240 (202) 208–7445.

Dated: January 24, 1992.

Eddie F. Brown,

Assistant Secretary, Indian Affairs.

[FR Doc. 92–2266 Filed 1–29–92; 8:45 am]

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federal register

Thursday
January 30, 1992

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 172

Aspartame; Denial of Request for Hearing on Final Rules; Food Additives Permitted for Direct Human Consumption; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 87F-0240 and 85F-0346]

Aspartame; Denial of Request for Hearing on Final Rules

AGENCY: Food and Drug Administration.

ACTION: Final rule; denial of request for hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing on the final rules that amended the food additive regulations to authorize the use of aspartame as a sweetener in frozen dairy and nondairy frostings, toppings, and fillings and in frozen, ready-to-thaw-and-eat cheesecakes, fruit, and fruit toppings. After reviewing the objections to the two final rules and the request for a hearing, FDA has concluded that no genuine issues of material fact have been raised that would justify a hearing. In addition, FDA is overruling other objections to the final rule for which there were no hearing requests because the agency has addressed similar objections in prior administrative proceedings concerning aspartame.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9528.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 2, 1989 (54 FR 23646 through 23647), FDA issued final rules that amended § 172.804(c) (21 CFR 172.804) of the food additive regulations by adding new paragraphs (c)(19) and (c)(20). Section 172.804(c)(19) authorizes the use of aspartame as a sweetener in frozen ready-to-thaw-and-eat cheesecakes, fruit, and fruit toppings. This rule responded to a petition filed by Foodways National, Inc. Section 172.804(c)(20) authorizes the use of aspartame as a sweetener in frozen dairy and nondairy frostings, toppings, and fillings. This rule responded to a petition filed by Foodways National, Inc., and the NutraSweet Co.

In accordance with 21 U.S.C. 348(f), four consumers and one consumer group filed objections to the final rules for aspartame. The aspartame Consumer Safety Network (ACSN), the consumer group, also requested a hearing on its objections. The agency's response to each objection and the request for a hearing is provided below.

II. Standard for Granting a Hearing

The Criteria for deciding whether to grant or deny a hearing are stated in 21 CFR 12.24(b). The regulation states that a hearing will be granted when the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 314.300, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing, are met.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214-215 (1980), *reh. den.*, 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-621 (1973). An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. *Georgia Pacific Corp.* v. *U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971). Stated another way, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." *Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. See *Citizens for Allegan Country, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality are validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

> The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.
>
> *Retail Clerks Union, Local 1401, R.C.I.A.* v. *NLRB*, 463 F. 2d 316, 322 (DC Cir. 1972). (See *Costle* v. *Pacific Legal Foundation, supra* at 1106; See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F. 2d 804 (DC Cir. 1966)).

III. Analysis of Request for Hearing

The ACSN requested that FDA convene a public hearing to receive and evaluate evidence relevant to its objections on four issues. These four issues are: That an aspartame double blind challenge test (Ref. 1) is erroneous; that pilots have lost their medical

certification to fly due to adverse reactions resulting from their consumption of aspartame; that the labeling of aspartame products will not protect individuals with phenylketonuria (PKU), or other sensitive individuals, when these products are served in the home and other social settings; and that pregnant patients are not being warned that aspartame consumption during pregnancy can cause mental retardation and other birth defects.

A. Adverse Reactions to Aspartame

ACSN's first objection challenged the reliability of a double blind test (Ref. 1) reporting that aspartame is unlikely to produce headaches at any greater rate than placebo and implicitly asserted that aspartame causes a wide range of adverse reactions in consumers. In support of this objection, ACSN submitted three letters, published in the New England Journal of Medicine, which reported deficiencies in the study's experimental design. In addition, ACSN submitted news articles, as well as some physician case reports, reporting that some consumers develop headaches after consuming aspartame-containing products.

The study in question was performed by Schiffman, et al., at Duke University. The study was a double blind crossover design in which the investigators administered capsules containing aspartame, at a dosage of 30 milligrams per kilogram of body weight, to 40 human subjects, most of whom had a family or personal history of allergic reactions. In addition, each of the test subjects had previously reported suffering a headache within 24 hours of ingesting aspartame. Thirty-five percent of the subjects reported headaches after taking aspartame, while 45 percent reported headaches after a placebo. No other reactions occurred. The investigators concluded that the study demonstrated that a patient ingesting aspartame is no more likely to suffer a headache than when receiving a placebo.

FDA is denying ACSN's first objection for the following reasons. First, the results of the study by Schiffman, et al., are consistent with the agency's conclusion that aspartame is safe. FDA did not rely upon this study, however, as the basis (or as part of the basis) for the agency's safety determination. Thus, even if the study must be disregarded because it is flawed as ACSN has alleged, this will not alter the foundation underlying FDA's conclusion that aspartame is safe. Therefore, establishment of ACSN's claims of design deficiency would not require the revocation of the aspartame regulations in question. Accordingly, FDA is overruling ACSN's first objection and denying its hearing request on this issue. 21 CFR 12.24(b)(4).

Second, FDA is overruling ACSN's first objection and denying the hearing request to the extent that the objection asserts that aspartame causes a wide range of adverse reactions. The data ACSN filed in support of its hearing request on this issue were in the form of physician case reports and individual testimonials. In previous proceedings on aspartame in November 1986, in which the agency denied a petition of the Community Nutrition Institute (CNI) to revoke all uses of aspartame (Ref. 2), FDA evaluated the use of individual complaints and case reports to determine whether a causal link exists between aspartame consumption and alleged adverse effects of the sweetener. The agency concluded that only well-controlled clinical trials focusing on specific endpoints could provide evidence for the existence of such a link. (Indeed, the United States Supreme Court has characterized anecdotal evidence as "treacherous." *Weinberger v. Hynson, Westcott and Dunning*, 412 U.S. 609,629 (1973).) Accordingly, the data and information submitted by ACSN are not reliable and thus, cannot serve as the basis for a hearing. 21 CFR 12.24(b)(2).

B. Seizures and Adverse Reactions of Airline Pilots

ACSN's second objection asserts that "hundreds of pilots have reported adverse reactions including grand mal seizures" and that many pilots have lost their certification to fly because of consumption of aspartame. In support of this second objection, ACSN submitted individual testimonials and case reports allegedly reflecting untoward reactions to aspartame, news articles on pilots and aspartame, and letters from aviation industry consultants.

FDA is overruling ACSN's second objection and denying its hearing request on this issue because the agency has previously considered in prior administrative proceedings on aspartame whether consumption of the sweetener causes seizures. Specifically, in responding in November 1986, to the CNI petition to revoke aspartame's approvals, FDA considered the possible link between aspartame consumption and seizure onset. The agency concluded that there was no reliable evidence from controlled clinical trials or other research that aspartame consumption is not safe (Ref. 2), a position subsequently reiterated in the agency's March 2, 1988, denial of a hearing request on amendments to the aspartame regulation (53 FR 6595 and 6597, March 2, 1988). Once an issue has been considered in a prior proceeding, a party is estopped from raising that same issue in a subsequent proceeding in the absence of new evidence.

In the present case, ACSN's objection neither identifies nor contains any reliable new data that would provide a basis for reconsideration of this factual issue by FDA. ACSN submitted only individual testimonials and case reports to support its assertions. This information is simply more of the type previously submitted in support of the alleged link between aspartame and various adverse reactions and, as noted in the discussion of objection 1, is not a reliable basis for determining a link between consumption of aspartame and such reactions. In the absence of new, reliable information, FDA need not hold a hearing on this factual issue. 21 CFR 12.24(b)(2).

C. Lack of Warning to PKU Children and Adults

ACSN's third objection asserted that PKU children and adults, as well as others wishing to avoid aspartame, will be unable to do so because there will be no warning label on aspartame-containing foods when served in the home and other social settings. ACSN also asserted that there are 20 million PKU gene carriers who are also at risk from consumption of aspartame. In support of this third objection, ACSN filed a sheet "Facts You Should Know About Aspartame or NutraSweet."

FDA is overruling this objection and denying ACSN's request for a hearing on this issue because the issue has previously been considered by FDA in prior proceedings on aspartame. ACSN's assertion that PKU adults and children will be unable to avoid aspartame if the sweetener is permitted in frozen, ready-to-eat cheesecakes, fruits, and fruit toppings is simply a restatement of the basic issue of aspartame's safety when eaten in moderation by average consumers. In a number of prior administrative proceedings, including the final decision of the Commissioner of Food and Drugs on aspartame's initial approval (46 FR 38285, July 24, 1981), the denial of the hearing request on aspartame's approval for use in carbonated beverages (49 FR 6672, February 22, 1984), and the November 21, 1986, denial of CNI's citizen petition to revoke all approved uses of aspartame (Ref. 2), FDA considered the safety of aspartame and concluded that there is a reasonable certainty of no harm from consumption of the additive.

ACSN has neither identified nor filed new reliable data or information to support its assertions on this point. In view of the prior consideration and in the absence of new data, no hearing need be held on this factual issue.

FDA is also denying ACSN's third objection to the extent that it asserts that PKU heterozygotes are at risk from consumption of aspartame. First, ACSN did not identify or file any data or information in support of this aspect of its third objection. Therefore, no hearing is required to be held on this issue. 21 CFR 12.24(b)(2). In addition, in the context of the Commissioner's final decision on aspartame, FDA concluded that there is no evidence that PKU heterozygotes are adversely affected by ingestion of aspartame (46 FR 38285 at 38287–38288, 38290–38291, and 38303–38305). The agency is not required to hold a hearing where, as here, the same issue was raised and considered in a prior proceeding and the objector has filed no new data or information.

D. Risk of Aspartame Use During Pregnancy

ACSN's fourth objection asserts that use of aspartame during pregnancy can cause mental retardation and other birth defects. ACSN asserts that Drs. Louis Elsas and William Partridge have warned against aspartame use during pregnancy. However, ACSN did not identify or file data or other information in support of this objection.

The agency is denying ACSN's fourth objection for two reasons. First, as noted, ACSN filed no data or other information to support its assertions about aspartame's relationship to birth defects. A hearing will not be granted on the basis of mere allegations or general descriptions of positions. 21 CFR 12.24(b)(2).

Secondly, in its prior decisions on the safety of aspartame, FDA considered the risks that high levels of the amino acid phenylalanine pose to the developing fetus (46 FR 38285 at 38290–38291 and 38303–38305, July 24, 1981; 53 FR 6595 at 6598–6600, March 2, 1988). At that time, FDA explained that eliminating aspartame from new products is an ineffective means of preventing birth defects because there are multiple sources of dietary phenylalanine, of which aspartame is only a relatively minor one. Thus, to prevent retardation and birth defects from elevated phenylalanine blood levels, the cause of the elevation must be diagnosed and all dietary sources of phenylalanine restricted. ACSN has filed no new data or information that dispute FDA's previous findings on this factual issue. In such circumstances, a hearing need not be granted.

IV. Analysis of Other Objections

In addition to ACSN, four consumers filed objections to the final aspartame rules, but did not request a hearing on any of these objections. Because there was considerable overlap, FDA has combined the objections in the agency's response to them set out below.

A. Lack of Comprehensive Human Testing

One objection asserted that FDA has not been provided with comprehensive human test data or studies to establish the safety of aspartame. In support of this assertion, the objection stated that: (1) Rodents do not metabolize "aspartic and phenylalanine acids" in the same manner as humans; (2) FDA overrode the objections and recommendations of the 1975 and 1977 FDA Task Forces, and the 1980 Public Board of Inquiry on aspartame; (3) FDA considered the monkey study pivotal and that this study demonstrated the toxicity of aspartame; and (4) there are an increasing number of consumer reports of the harmful effects of aspartame usage which FDA is ignoring. To support this objection, the objector submitted a chronology from 1969 to 1986 that arguably relates to aspartame, a list of scientists who have conducted studies on the reported adverse effects of aspartame, and a list of publications dealing with aspartame's safety.

The agency has considered this first objection and, as discussed below, has determined that it provides no basis for reconsideration or alteration of the final rules at issue. First, the objector did not identify any data or other information to support its assertion that additional studies of aspartame in humans are necessary to establish the safety of the additive. In fact, there have been extensive clinical studies of aspartame, including tests in children, infants, and obese, diabetic, and normal adults; doses of aspartame in these studies have ranged from very large acute doses to more moderate subchronic (13 to 28 weeks) doses. FDA considered and discussed these human test data in prior proceedings involving aspartame (46 FR 38285 at 38292–38294, July 24, 1981; 49 FR 6672 at 6680, February 22, 1984; 48 FR 31376 at 31381, July 8, 1983). Importantly, these clinical studies are only a portion of the scientific data that support the agency's determination that the additive is safe, which data are discussed in the Commissioner's final decision (46 FR 38285 at 38289–38301, July 24, 1981). Likewise, the objector filed no data or information to support its claims concerning rat metabolism. Finally, the objector provided only anecdotal case reports to support its assertion that aspartame has harmful effects, which, as discussed above, are not an adequate basis for support. Accordingly, FDA is overruling this objection.

B. Change in ADI for Aspartame

A second objection asserted that no safe level of aspartame has been established and that FDA originally set the safe maximum daily intake for aspartame at 20 mg/kg/day and then increased it to 50 mg/kg/day without requiring new testing. The objection further asserts that aspartame should have been examined and tested as a drug instead of a food additive. The objector relies upon the data and information identified in objection 1 above to support this objection.

FDA has considered this second objection and has determined, as set out below, that it provides no basis for reconsideration or alteration of the final rules at issue.

First, no objector provided any data or other information to demonstrate that the current acceptable daily intake (ADI) of 50 mg/kg of body weight/day is inadequate. The objector correctly asserts that the original aspartame ADI was 20 mg/kg of body weight/day. However, additional clinical testing data were provided by the petitioner to support a revision of the ADI to 50 mg/kg of body weight/day. In prior administrative proceedings concerning aspartame, FDA discussed the basis for this revision of the ADI (49 FR 6672 at 6678, February 22, 1984). Second, the objector provided no support for its assertion that aspartame should have been tested as a drug. To the contrary, aspartame meets the definition of a food additive, 21 U.S.C. 321(s), not the definition of a drug, 21 U.S.C. 321(g), in the Federal Food, Drug, and Cosmetic Act and thus, should be tested, evaluated, and regulated as such. Accordingly, because no objector has provided any basis for impeaching the current ADI or for testing and regulating aspartame as a drug, FDA is overruling this second objection.

C. Risks Posed by DKP and Methanol

A third objection expressed a concern about two breakdown products of aspartame: Diketopiperazine (DKP) and methanol. The objection asserted that DKP is a cancer-causing substance that occurs in large amounts if aspartame is stored for an extended period of time, especially at elevated temperatures. The objection also challenges FDA's position that the methanol that results from

aspartame consumption is not harmful because methanol is a component of fruit juices and a few vegetables; the objector claims that this reasoning is faulty because methanol in these natural products is safely bound by pectin and is always accompanied by ethanol, which is claimed to block any damaging effects of methanol. In support of this objection, the objector filed an outline of the toxicity of methanol, including the quantity ingested from the degradation of aspartame and a list of the breakdown products of aspartame.

FDA has considered this third objection and has determined, as set out below, that it does not provide a basis for reconsideration or alteration of the final rules in question.

First, FDA has previously considered the possible effects of DKP from metabolism of aspartame (48 FR 31376 at 31380, July 8, 1983; 49 FR 6672 at 6677, February 22, 1984). FDA agrees that DKP concentration may increase if aspartame is stored under abusive conditions. However, based on well-conducted chronic bioassays in two rodent species, FDA previously concluded that the acceptable daily intake of DKP exceeds any dietary exposure that is likely to result from aspartame consumption (48 FR 52899 at 52901, November 23, 1983). No objector filed any data or information to support its assertion to the contrary. In such circumstances, there is no basis to reevaluate the final rules at issue.

Second, FDA has also previously considered the effect, if any, that methanol has on the safety of aspartame consumption. FDA determined that the amount of methanol due to exposure to aspartame is well below levels that produce the earliest signs of methanol toxicity (49 FR 6672 at 6677, February 22, 1984). Furthermore, the levels of methanol from ingesting aspartame is the same magnitude as that presented by other food sources, such as fruit juices and tomatoes; those levels of methanol are easily eliminated or metabolized by the body. No objector provided any new data or information to contradict FDA's previous evaluation of this issue. Accordingly, FDA is overruling this objection.

D. Absence of Warning Labels on Aspartame

A fourth objection questioned the absence of a label warning pregnant women to avoid products containing aspartame and asserted that aspartame causes fetal damage and mental retardation. This objection also questioned the usefulness of the phenylketonuria labeling for products containing aspartame and appeared to imply that certain carriers of the PKU gene are at risk from consumption of aspartame. No objector provided any specific data or information to support the claim that pregnant women cannot safely consume aspartame or that PKU gene carriers are at risk from consumption of aspartame.

In responding above to the ACSN request for a hearing on these same issues, FDA noted that the agency has addressed both issues in prior administrative proceedings on aspartame and that in the absence of new data or information, no hearing need be held. Likewise, in the absence of new data or information, there is no basis for reconsideration or alteration of the final rules at issue here. Therefore, FDA is overruling this fourth objection.

V. Conclusion

As set out above, FDA concludes that no new issues or reliable evidence have been presented to support the objections to the final rules providing for the use of aspartame in frozen desserts and frozen frostings, toppings, and fillings. Furthermore, when analyzed according to the proper standards, ACSN has not justified a hearing on its objections to the final rules.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Schiffman et al., New England Journal of Medicine, 317:1181–1185, 1989.

2. Letter dated November 21, 1986, from John M. Taylor to James S. Turner.

Dated: January 24, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92–2235 Filed 1–29–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 172

[Docket No. 87F–0277]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame as a sweetener in malt beverages of less than 7 percent ethanol by volume and containing fruit juice. This action is in response to a petition filed by The Stroh Brewery Co.

DATES: Effective January 30, 1992; written objections and requests for a hearing by March 2, 1992.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF–333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9528.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 14, 1987 (52 FR 38144), FDA announced that a food additive petition (FAP 7A4029) had been filed by the Stroh Brewery Co., 100 River Pl., Detroit, MI 48207–4291, proposing that § 172.804 Aspartame (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in malt beverages of less than 7 percent ethanol by volume and containing fruit juice.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in 21 CFR 172.804(c) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 2, 1992 file with